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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,724	06/14/2002	Ikuo Nishimoto	082377-00000US	6929

7590 05/24/2006
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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/088,724	Applicant(s) NISHIMOTO, IKUO	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8,13,16,20-22,27-30,35-38,43 and 45-49 is/are pending in the application.
4a) Of the above claim(s) 47-49 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,4,6-8,13,20-22,27,36-38,43 and 45 is/are allowed.
- 6) ☒ Claim(s) 5, 16, 28-30, 35 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/14/5</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 2, 5, 6, 16, 20, 28, 36 have been amended, claim 15 has been canceled and claims 46-49 have been added as requested in the amendment filed on April 07, 2006. Following the amendment, claims 1, 2, 4-8, 13, 16, 20-22, 27-30, 35-38, 43 and 45-49 are pending in the instant application.

2. Newly submitted claims 47-49 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 47-49 encompass gene therapy as directed to compositions comprising DNA formulated for pharmaceutical, clinical purposes. In contrast, the instant invention is directed to polypeptides, encoding polynucleotides and methods of using polypeptides in pharmaceutical composition. For reasons of record fully explained in the Paper mailed on September 15, 2003, claims directed to gene therapy represent an invention, which is independent and distinct from the instant invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 47-49 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 2, 4-8, 13, 16, 20-22, 27-30, 35-38, 43 and 45-46 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on April 07, 2006 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

6. Claims 16, as amended, and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement essentially for reasons of record as applied to claims 15 and 16 in the previous communications of record.

Briefly, the claims are directed to pharmaceutical compositions comprising the polypeptides of the instant invention in the amount effective to treat Alzheimer's disease or any neurodegenerative disease associated with amyloid pathology (claim 46). However, the instant specification fails to provide enough guidance as how to practice Applicant's invention. At pp. 8-11 of the Response Applicant presents arguments that appear to be intended to rebut the Examiner's position that Alzheimer's disease is not limited only to amyloid pathology. Unfortunately, the full logic of Applicant's reasoning is not understandable. Nevertheless, there appears to be no clear factual support or sound scientific explanation presented within Applicant's Response to support a conclusion that limited information on beneficial effects of the polypeptide of SEQ ID NO: 63 on experimental survival of neuronal cells can be directly extrapolated to therapeutic means of treatment of Alzheimer's disease or any neurodegenerative disease characterized by amyloid pathology. The Examiner maintains the position that in view of the art recognition of complexity factors involved in the etiology and course of development and

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progression of Alzheimer's disease, the instant specification clearly lacks enablement for the pharmaceutical composition as claimed in claims 16 and 46.

Therefore, for reasons fully explained earlier and reasons above, the instant rejection is maintained.

New grounds of rejection necessitated by amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 5, 28-30 and 35, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. Claim 5, as amended, is vague and indefinite in section (b), which does not make sense. Applicant is advised to rewrite the section in a way similar to section (b) of claims 2 and 6 (see the placement of limitation "in such a way that" within the text of the claim).
9. Claim 5 is further vague and ambiguous for recitation "wherein the DNA does not comprise the sequence of SEQ ID NO: 4". According to the instant specification, DNA of SEQ ID NO: 4 encodes a protein (humanin) of SEQ ID NO: 5 (see page 45), which is recited among the sequences in section (c). Thus, these two limitations appear to contradict each other and, therefore, render the claimed subject matter indefinite.
10. Claims 28-30 and 35 are indefinite for being dependent from indefinite claim.

Conclusion

11. Claims 1, 2, 4, 6-8, 13, 20-22, 27, 36-38, 43 and 45 are allowed. Claims 5, 16, 28-30, 35 and 46 are rejected.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

May 17, 2006